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EXAMINER

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte ELLEN L. BERG, EUGENE C. BUTCHER,
and JENNIFER MELROSE

Appeal 2010-000164
Application 10/716,349
Technology Center 1600

Before DONALD E. ADAMS, DEMETRA J. MILLS, and ERIC GRIMES,
Administrative Patent Judges.

MILLS, *Administrative Patent Judge.*

DECISION ON APPEAL¹

This is an appeal under 35 U.S.C. § 134. The Examiner has rejected the claims for indefiniteness, anticipation and obviousness. We have jurisdiction under 35 U.S.C. § 6(b).

¹ The two-month time period for filing an appeal or commencing a civil action, as recited in 37 C.F.R. § 1.304, or for filing a request for rehearing, as recited in 37 C.F.R. § 41.52, begins to run from the “MAIL DATE” (paper delivery mode) or the “NOTIFICATION DATE” (electronic delivery mode) shown on the PTOL-90A cover letter attached to this decision.

STATEMENT OF THE CASE

The following claims are representative and read as follows:

17. A method for analyzing a candidate compound for a biological activity of interest, the method including:
- contacting a test mammalian cell culture with the compound, wherein the culture includes a plurality of factors wherein a plurality of signaling pathways are induced by the presence of the factors;
 - measuring at least two parameters associated with the plurality of pathways and comparing the measurement of the at least two parameters with the measurement from a control cell culture lacking the compound, and
 - recording the measurements of the test cell culture and the control cell culture to produce a biological dataset profile, wherein the biological dataset profile is indicative of the pathways that are active in the cell culture.
22. The method of Claim 17, further including the step of compiling a plurality of the biological dataset profiles in a database.

Cited References

The Examiner relies on the following prior art references:

Friend et al. US 6,801,859 B1 Oct. 5, 2004

Chung et al., *Characterization of Primary Rabbit Kidney Cultures that Express Proximal Tubule Functions in a Hormonally Defined Medium*, 95 JOURNAL OF CELL BIOLOGY 118-126 (1982).

Rice et al., *Development of a High Volume Screen to Identify Inhibitors of Endothelial Cell Activation*, 241 ANALYTICAL BIOCHEMISTRY 254-259 (1996).

Grounds of Rejection

1. "Claim 22 is rejected under 35 U.S.C. [§] 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention." (Ans. 3.)

2. Claims 17 and 22 are rejected under 35 U.S.C. § 102(e) as being unpatentable over Friend as evidenced by Chung. (*See id.* at 4-6.)
3. Claims 17 and 19-22 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Friend in view of Chung. (*See id.* at 6-9.)
4. Claims 17 and 19-22 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Friend in view of Rice. (*See id.* at 9-11.)

FINDINGS OF FACT

The Examiner's findings of fact are set forth in the Answer at pages 3-11.

Discussion

1. "Claim 22 is rejected under 35 U.S.C. [§] 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention." (*Id.* at 3.)

The Examiner argues that claim 22 is dependent upon claim 17 in which a single dataset profile is produced. The Examiner argues that because multiple dataset profiles are not recited in claim 17 that claim 22 is vague with respect to the source of the dataset profiles.

"The test for definiteness is whether one skilled in the art would understand the bounds of the claim when read in light of the specification." *Miles Laboratories, Inc. v. Shandon, Inc.*, 997 F.2d 870, 875 (Fed. Cir. 1993). Claims are in compliance with 35 U.S.C. § 112, second paragraph, if "the claims, read in light of the specification, reasonably apprise those skilled in the art both of the utilization and scope of the invention, and if the

language is as precise as the subject matter permits.” *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1385 (Fed. Cir. 1986).

We disagree with the Examiner and find that claim 22 recites with sufficient particularity and distinctness the claimed subject matter when read in view of the Specification. Claim 22 *further includes* “a step of compiling a plurality of the biological dataset profiles in a database.” We find that one of ordinary skill in the art would reasonably understand that the multiple dataset profiles of claim 22 are those individually recited in claim 17.

The rejection is reversed.

2. Claims 17 and 22 are rejected under 35 U.S.C. § 102(e) as being unpatentable over Friend as evidenced by Chung. (*See* Ans. 4-6.)
3. Claims 17 and 19-22 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Friend in view of Chung. (*Id.* at 6-9.)

ISSUE

The Examiner concludes that

It would have been obvious to one of ordinary skill in the art to modify the method of Friend et al. who shows a method of screening compounds using cultured cell lines, the results of which are used to produce response profiles for compounds, with the kidney cell culture medium and primary kidney cell line of Chung et al. because Chung et al. shows hormonally-defined culture medium provides the benefit of significantly improving the culture conditions of primary kidney epithelial cells and the primary kidney cells grown in the defined medium have a closer resemblance to the tissue from which they are derived.

(*Id.* at 8-9.)

Appellants argue that Friend does not disclose employing a culture “comprising at least two factors or in which a plurality of pathways is activated,” as claimed. (App. Br. 5.) Appellants argue that in the present invention “a test agent contacts cells in culture that are stimulated in multiple pathways by the addition of at least two factors.” (*Id.*) Appellants argue that Chung does not specify that “a plurality of signaling pathways [are] induced.” (*Id.*) Thus, as we understand it, Appellants argue that the cited prior art does not disclose “contacting a test mammalian cell culture with the compound, wherein the culture includes a plurality of factors wherein a plurality of signaling pathways are induced by the presence of the factors; [and] measuring at least two parameters associated with the plurality of pathways,” as claimed. (Claim 17.)

The issue is: Does the cited prior art disclose “contacting a test mammalian cell culture with the compound, wherein the culture includes a plurality of factors wherein a plurality of signaling pathways are induced by the presence of the factors; [and] measuring at least two parameters associated with the plurality of pathways,” as claimed? (*Id.*)

PRINCIPLES OF LAW

In order for a prior art reference to serve as an anticipatory reference, it must disclose every limitation of the claimed invention, either explicitly or inherently. *See In re Schreiber*, 128 F.3d 1473, 1477 (Fed. Cir. 1997).

“In rejecting claims under 35 U.S.C. § 103, the examiner bears the initial burden of presenting a *prima facie* case of obviousness. Only if that burden is met, does the burden of coming forward with evidence or argument shift to the applicant.” *In re Rijckaert*, 9 F.3d 1531, 1532 (Fed.

Cir. 1993) (citations omitted). In order to determine whether a prima facie case of obviousness has been established, we consider the factors set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 17 (1966): (1) the scope and content of the prior art; (2) the differences between the prior art and the claims at issue; (3) the level of ordinary skill in the relevant art; and (4) objective evidence of nonobviousness, if present.

ANALYSIS

The rejections as to whether claims 17 and 22 are anticipated by an inherent disclosure in Friend as evidenced by growth promoting factors in the medium of Chung, or obvious over Friend in view of growth promoting factors in the medium of Chung, present similar issues, so we will address these rejections together. The Examiner concludes that

It would have been obvious to one of ordinary skill in the art to modify the method of Friend et al. who shows a method of screening compounds using cultured cell lines, the results of which are used to produce response profiles for compounds, with the kidney cell culture medium and primary kidney cell line of Chung et al. because Chung et al. shows hormonally-defined culture medium provides the benefit of significantly improving the culture conditions of primary kidney epithelial cells and the primary kidney cells grown in the defined medium have a closer resemblance to the tissue from which they are derived.

(*Id.* at 8-9.)

We are not persuaded by the Examiner's argument. We do not find that the Examiner has articulated or provided sufficient evidence in the prior art of the step of measuring at least two parameters associated with the

plurality of pathways induced by the presence of factors in the cell culture, as claimed. We agree with Appellants that the cited prior art fails to disclose the steps of contacting a test mammalian cell culture with a compound, wherein the culture includes a plurality of factors wherein a plurality of signaling pathways are induced by the presence of the factors; and particularly, measuring at least two parameters associated with the plurality of pathways, as claimed.

The anticipation and obviousness rejections based on Friend and Chung are reversed.

4. Claims 17 and 19-22 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Friend in view of Rice.

The Examiner argues that

It would have been obvious to one of ordinary skill in the art to modify the method of Friend et al. who shows a method of screening compounds using cultured cell lines, the results of which are used to produce response profiles for compounds, with the primary cells and cytokine factors of Rice et al. because Rice et al. shows the role of endothelial cells activation in inflammatory diseases is critical and it would be advantageous to identify inhibitors of endothelial cell activation that will lead to useful therapeutics.

(*Id.* at 11.)

We are not persuaded by the Examiner's argument. We do not find that the Examiner has articulated or provided sufficient evidence in the prior art of the step of measuring at least two parameters associated with the plurality of pathways induced by the presence of factors in the cell culture,

as claimed. We agree with Appellants that the cited prior art fails to disclose the steps of contacting a test mammalian cell culture with a compound, wherein the culture includes a plurality of factors wherein a plurality of signaling pathways are induced by the presence of the factors; and particularly, measuring at least two parameters associated with the plurality of pathways, as claimed. (Claim 17.)

The obviousness rejection is reversed.

CONCLUSION OF LAW

The cited references do not support the Examiner's anticipation and obviousness rejections.

REVERSED

alw

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